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Notice of Allowability	Application No.	Applicant(s)	
	10/049,227	CLARKE ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

- 1. ☒ This communication is responsive to Amendment filed 09/05/06.
 - 2. ☒ The allowed claim(s) is/are 38-52,54-58,60-69,71 and 72.
 - 3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 - 1. ☒ Certified copies of the priority documents have been received.
 - 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

- 4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 - 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
- 6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>09/05/06 + 8-3-06</u> |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Bruce C. Zotter on 09/05/06.

The application has been amended as follows:

Claim 38, line 12, after the phrase "plug constituting a unitary part of one of the joined", the word "units" has been amended to "sub-units".

Claim 38, lines 15-16, the limitation "and said joined sub-units are secured together independently by a weld at the joint thereof" has been amended to " wherein the plug further comprises an end wall extending to the outer wall of the respective sub-units and is permanently secured by a weld,".

Claim 38, line 16, the word "that" has been amended to "wherein".

Claim 38, lines 16-17, the phrase "at least one sub-unit" has been deleted.

Claim 38, line 17, before the phrase "differs from the drug substance", the phrase "one of said two sub-units" has been inserted.

Claim 38, line 17, after the word "differs", the phrase "in composition and/or release characteristics" has been inserted.

Claim 38, lines 17-18, the phrase "at least one other sub-unit" has been amended "the other of said two sub-units".

Claim 67, lines 17-20, the limitation “welded together to provide an assembled dosage form, and wherein the drug substance in at least of the dosage forms of the set differs from the drug substance present in another of the sub-units of the set” has been amended to “joined to at least one other sub-unit by a joint comprising a plug constituting a unitary part of one of the joined sub-units and a socket formed as a unitary part in the other of the joined sub-units, wherein the plug further comprises an end wall extending to the outer wall of the respective sub-units and is permanently secured by a weld, and wherein the drug substance present in one of said two sub-units differs in composition and/or release characteristics from the drug substance present in the other of said two sub-units”.

Claim 68, lines 17-18, the limitation “and wherein the first drug substance is different from the second drug substance” has been amended to “wherein the plug further comprises an end wall extending to the outer wall of the respective drug substance-containing capsules and is permanently secured by a weld, and wherein the drug substance present in one of said drug substance-containing capsules differs in composition and/or release characteristics from the drug substance present in the other of said drug substance-containing capsules”.

The following is an examiner's statement of reasons for allowance:

The closest prior arts, Glassman and Goodhart, do not teach capsules comprising plug that further comprises an end wall extending to the out wall of the capsule/sub-units, and joint together permanently by a weld. These features provide

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the claimed capsule the advantageous results of having different drugs compositions in different compartment, as well as different release profile.

Correspondence

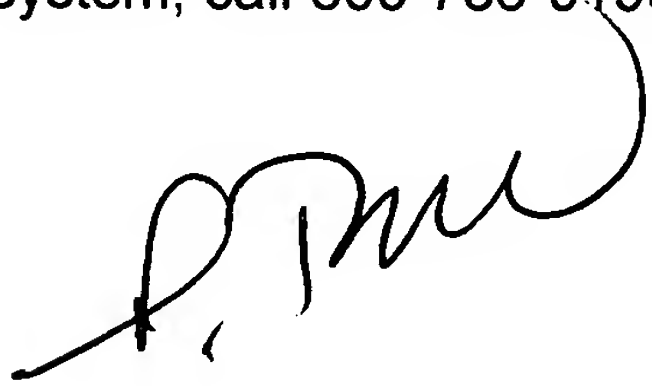
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'S. Tran', with a large, sweeping loop at the end.

S. Tran
Primary Examiner
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